Remarks

Claims 72-89 are pending in the subject application. By this Amendment, Applicants have amended claims 72 and 81. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 72-89 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Examiner Landsman was contacted on January 29, 2009 regarding the indication that no priority to GB 0325038.8 has been recorded on the Bibliographic Data Sheet. Examiner Landsmann confirmed that GB 0325038.8 is listed on the Bibliographic Data Sheet and that no further information or action was required by the Applicants.

The Examiner has also objected to the title of the invention on the grounds that it does not adequately describe the claimed subject matter. In accordance with the Examiner's suggestion, Applicants have amended the title of the invention to "Isolated INSP163 Protein." Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

The subject specification has been objected to on the grounds that it does not comply with 37 CFR §1.821(d). Specifically, no sequence identification has been provided for the sequences in Table 2 on page 66 of the subject specification. By this Amendment, Applicants have amended the specification to include the sequence identifier numbers. Additionally, the Examiner indicates that Figures 2 and 3 contain sequences without appropriate SEQ ID NOs. By this Amendment, Applicants have amended the Brief Description of Figures 2 and 3 to include the sequence identifier numbers. In addition, a Submission of Sequence Listing Under §1.821, including a replacement sequence listing on paper and a computer readable format, is attached. Applicants respectfully assert that no new matter has been added by any of the amendments. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The Office Action indicates that the brief description of Figure 3 should be amended to recite all the panels of the figure. Applicants acknowledge the Examiner's careful review of the specification. The brief description has been amended to reflect "Figures 3A-3F" as suggested by the Examiner. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Although the Office Action indicates that no embedded hyperlinks and/or other forms of browser-executable codes are found, the subject application has been amended to correct one instance on the last line of page 25 of the subject specification. Applicants are not aware of any improper uses of trademark symbols. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 73-80 and 82-89 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants respectfully assert that the claims are in proper dependent form. However, by this Amendment, the claims have been amended to recite "An isolated polypeptide comprising: a) SEQ ID NO:34; or b) a fusion protein comprising SEQ ID NO: 34 and a heterologous sequence". Accordingly, reconsideration and withdrawal of the objection is respectfully requested as it is believed that this amendment renders this issue moot.

Claims 72-89 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. In addition, claims 72-89 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled on the grounds that the subject specification fails to teach a substantial utility for the claimed invention and, therefore, an ordinarily skilled artisan would not know how to use the claimed invention. The Office Action notes four (4) asserted utilities for the claimed polypeptides (*e.g.*, for diagnosis of a dysfunction associated with SEQ ID NO: 34; for the production of antibodies specific for SEQ ID NO: 34; for tissue localization; and for the identification of ligands and/or antagonists of SEQ ID NO: 34). The Office Action argues that each of these asserted utilities are not sufficient for patentability as the as-filed specification does not provide data demonstrating the biological activity/role of the claimed polypeptide and/or its significance. Applicants respectfully assert that the claimed invention has substantial utility and, therefore, is enabled.

The Patent Office must also articulate the factual assumptions and provide evidentiary support relied upon in establishing the *prima facie* showing. *See In re Gaubert*, 524 F.2d 1222, 1224, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (Accordingly, the PTO must do more than merely question operability—it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability). Furthermore, the lack of working

examples or methods that indicate that the claimed polypeptide is involved in any activity cannot, standing alone, be the basis for a lack of utility rejection under 35 U.S.C. 101 or 35 U.S.C. 112. *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.h.*, 945 F.2d 1546, 1553, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991). Applicants also note that compliance with the utility requirement of 35 U.S.C. § 101 and the enablement requirement of 35 U.S.C. § 112, first paragraph, does not turn on whether an example is disclosed (see M.P.E.P. §2164.02). Indeed, the Federal Circuit has held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 U.S.P.Q. 2d 1302, 1304 (Fed. Cir. 1987) (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 U.S.P.Q. 321, 325 (C.C.P.A. 1956)). Applicants submit that the Office Action has failed to meet this burden and submit that a *prima facie* showing that the claimed invention lacks patentable utility has not been made in this matter. Thus, reconsideration and withdrawal of the rejections is respectfully requested.

Applicants note that the application, as-filed, states that the claimed polypeptide has structural similarity to a number of polypeptides associated with lung tumors (COL8A1 and COL8A2) and arthritis/osteoarthritis (CORS-26 and BAFF; see pages 12-13). Additionally, Applicants note that the as-filed specification teaches that the claimed polypeptide can be used for the diagnosis of diseases, such as arthritis and osteoarthritis (see specification, page 17, line 25 through page 18, line 2). Co-pending application 11/912,432 indicates that overexpression of INSP-163 mRNA is associated with osteoarthritic tissues and lung cancer (see pages 25-30), thus supporting the asserted utility of the claimed polypeptide as being useful for the identification of various diseases, such as arthritis or osteoarthritis. Furthermore, the as-filed specification provides ample teachings with respect to how one skilled in the art would have used the claimed polypeptides for such purposes. For example, paragraph bridging pages 19-20 states:

> [T]he invention provides a method of diagnosing a disease in a patient, comprising assessing the level of expression of a natural gene encoding a polypeptide of the first aspect of the invention or the activity of a polypeptide of the first aspect of the invention in tissue from said patient and comparing said level of expression or activity to a control level, wherein a level that is different to said control level is indicative of disease. Such a method will preferably be carried out *in vitro*. Similar methods may be used for monitoring the therapeutic treatment of disease in a patient,

wherein altering the level of expression or activity of a polypeptide or nucleic acid molecule over the period of time towards a control level is indicative of regression of disease.

Thus, Applicants respectfully submit that the preponderance of evidence supports a finding that one skilled in the art would have reasonably believed the asserted utility of the claimed polypeptide set forth in the specification on the basis of the teachings provided therein and reconsideration and withdrawal of the rejection under 35 U.S.C. §101 and under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 72-89 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 44, 46 and 47 of copending Application No. 11/912,432. Applicants respectfully assert that the claims as amended herein are not obvious over the claims of the cited application. However, should the Examiner indicate allowable subject matter in the application, Applicants would consider filing a terminal disclaimer to address this rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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FCE/jb/sl
Attachments: Replacement pages 1-27 (Sequence Listing)
Submission of Sequence Listing Under §1.821